REMARKS

By this amendment, claims 15, 22, 24, and 41-45 are amended, and claims 46 and 47 are cancelled. There are now 39 claims pending. These are 1-5, 7-12, 15-19, 22-31 and 33-45. No new matter is introduced by the amendments and support for the amendments is found throughout the specification and in the previously filed claims. This response and amendment is timely filed in response to the Office Action mailed on January 11, 2007.

Applicant's representative thanks Examiner Henry and Supervisory Examiner Jiang for extending the courtesy of an interview on August 8, 2006. At that interview, it was agreed that a new Office Action on the merits would be sent and the June 20, 2006 Office Action sent following the September 26, 2005 response would be withdrawn. A new Office Action was mailed on December 22, 2006 which was subsequently withdrawn. The current Office Action was mailed January 11, 2007.

This application has special status. Applicant requested special status in a petition filed September 11, 2003. A status inquiry was filed January 19, 2007. The petition was granted January 24, 2007. In view of the late granting of this petition and the delays encountered in the prosecution of this application, Applicant requests expedited review of this response.

Rejection of Claims Under 35 U.S.C. § 112 (second paragraph)

Claims 15-19, 22, 24, 30, 33 and 41-47 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject which applicant regards as the invention. The Examiner asserted that the phrase "a condition associated with a hormonal change" in claims 15, 24 and 41-47, renders the claims indefinite. More specifically, the Examiner asserts that it is unclear what condition(s) are associated with a hormonal change and how this or these condition(s) must be related to the hormonal change to be considered as being associated with the hormonal change.

Applicant respectfully asserts that these terms are completely defined on pages 13 and 14 of the specification, and as explained in detail in the response filed September 26, 2005. In view

of this extensive disclosure in the specification, Applicant again asserts that the claims are not indefinite, the conditions are clearly stated, and that one of ordinary skill in the art would be able to practice the invention, as claimed. However, in the interest of advancing prosecution, Applicant has amended the claims to delete the words, "a condition associated with a hormonal change", without prejudice to pursue these claims in a continuation or subsequent patent application. The amendments to the claims render moot the rejection and Applicant requests withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection of Claims Under 35 U.S.C. § 103

Paradissis in view of Kostic

Claims 1-5, 7-12, 23, 25-29, 31 and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (U.S. Patent No. 5,494,678, hereinafter Paradissis) in view of Kostic (Archiv fuer Gynaekologie, 1965, 202 (1) pp 506-509, hereinafter Kostic).

The Examiner asserts that Paradissis discloses a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6, and vitamin B1 (emphasis added). In contrast, Applicant's composition does not contain vitamin B1 and is limited by the use of the language consisting of.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increase uterine contractions in force and frequency. The Examiner combined Kostic and Paradissis to assert that Kostic provides motivation to exclude vitamin B1 from Paradissis's composition and thereby derive Applicant's claimed composition. The Examiner asserts that it would have been obvious to one of ordinary skill in the art, in view of Paradissis and Kostic, to do the following: a) to make Paradissis's composition (for pregnant women); 2) to exclude vitamin B1 from Paradissis's composition in order to administer the composition to pregnant women, especially women with high risk pregnancy; and, 3) to use any amount or quantity of the components.

Applicant respectfully traverses this rejection. Kostic uses doses of vitamin B1 (100 mg) that are 50 to 100 times greater than disclosed by Paradissis (1-2 mg). Kostic, in the short three line abstract provided, gives 100 mg of vitamin B1 to women in labor after cervical dilation reached 3-4 cm in order to increase the force and frequency of uterine contractions. Paradissis's compositions include vitamin B1 and are designed to maximize fetal development and maternal health during each trimester of pregnancy (see Abstract), not to accelerate uterine contractions. One of ordinary skill in the art would not combine Kostic and Paradissis as they are addressing completely different issues.

One of ordinary skill in the art who might use Paradissis's composition for its intended purpose would not look to art teaching acceleration of labor by using 50-100 times the amount of vitamin B1 in Paradissis's composition, and then conclude that the 1 to 2 mg amount of vitamin B1 in Paradissis should be removed because it might accelerate labor. Kostic does not disclose, teach or suggest that vitamin B1 is not required in Paradissis's composition. Paradissis's composition, which includes vitamin B1, does not accelerate labor and cause premature birth. Accelerating labor would render Paradissis's composition inoperable for its intended purpose and could cause premature delivery, thereby endangering the health of the fetus and mother.

Accordingly, the cited art is improperly combined and the teachings of the cited art conflict. The cited art, alone or together, does not provide a suggestion or motivation to modify Paradissis's composition by deleting vitamin B1 and deriving Applicant's invention, as claimed. The prior art does not suggest the desirability of the claimed compositions.

Paradissis includes vitamin B1 in every single disclosed embodiment for each trimester and varies the amount of B1 depending on the use in each trimester. Deletion of vitamin B1 from every embodiment disclosed by Paradissis could render these compositions of Paradissis unsatisfactory for their intended purpose or change their principle of operation, as supplements to be administered during the different trimesters of pregnancy.

Applicant's claimed composition is effective. Applicant conducted a study concerning administration of one embodiment of the present invention to post menopausal women. This embodiment consisted of folic acid (1.6 mg), vitamin B12 (425 mcg), vitamin B6 (25 mg), vitamin D (400 IU) and calcium (400 mg), administered in two pills per day. Plasma homocysteine levels were measured before and six weeks after administration of the vitamin composition. The results show greater than a 20% reduction in plasma homocysteine levels in the postmenopausal women receiving the vitamin. These striking and unexpected results demonstrate the remarkable efficacy of Applicant's claimed vitamin composition. The cited art, alone or in combination, does not teach, suggest or provide motivation to make Applicant's composition, as claimed, which is efficacious at least in post-menopausal women to reduce homocysteine levels.

For at least all of the reasons cited above, Applicant respectfully asserts that the rejection of claims 1-5, 7-12, 23, 25-29, 31 and 34-40 under 35 U.S.C. § 103(a) over Paradissis in view of Kostic has been overcome and requests its withdrawal.

Paradissis in view of Boros et al. or Boros

Claims 1-5, 7-12, 23, 25-29, 31 and 34-40 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Paradissis et al. (U.S. Patent No. 5,494,678, hereinafter Paradissis) in view of Boros et al. (Proc. Am. Assoc. Can. Res. Ann. Meeting (March 2000) No. 41, pp. 666, hereinafter Boros et al.) or Boros (Anticancer Research, (2000 Vol. 29, No. 3B, pp 2245-2248, hereinafter Boros). The Examiner asserts that since Boros et al. disclose that vitamin B1 promotes the growth of cancer, one of ordinary skill in the art would be motivated to remove vitamin B1 from Paradissis's composition and derive Applicant's claimed compositions. The rationale provided by the Examiner appears to be that Boros or Boros et al. would lead one of skill in the art would to delete vitamin B1 from Paradissis's composition "so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1" (emphasis added).

Applicant respectfully traverses this rejection. Boros et al. is in a completely different field than Paradissis and is improperly combined with Paradissis. Boros et al. (Proc. Am. Assoc. Can. Res. Ann. Meeting (March 2000) No. 41, pp. 666) investigate the effects of vitamin B1 on the enzyme transketolase which is involved in the pentose cycle. Boros et al. used Erlich's ascites tumor cells hosted in mice and injected vitamin B1 intraperitoneally and observed an increase in tumor cells. Intraperitoneal administration of vitamin B1 to tumor bearing mice is non-analogous art to Paradissis's filed of oral vitamins in pregnant women for promotion of fetal and maternal health. One of ordinary skill in the art of Applicant's claimed invention would not look to Boros et al. using tumor bearing mice in the field of cancer cell biology for any guidance, suggestion or motivation to remove vitamin B1 from Paradissis's composition and derive Applicant's claimed compositions. Boros et al. does not provide any motivation or suggestion to modify Paradissis's composition. Boros et al. is improperly combined with Paradissis in this rejection and the rejections should be withdrawn.

Paradissis includes vitamin B1 in every single disclosed embodiment and uses his vitamin compositions to promote fetal and maternal health through the three trimesters of pregnancy, not to increase the risk of cancer in the fetus or mother. Deletion of vitamin B1 from every embodiment disclosed by Paradissis could render these compositions of Paradissis unsatisfactory for their intended purpose or change their principle of operation, as supplements to be administered during the different trimesters of pregnancy.

Applicant also asserts that the rationale provided by the Examiner, which appears to be that one of skill in the art would want to delete vitamin B1 from Paradissis's composition "to prevent the promotion of possible cancer or tumor conditions", is based on speculation. Boros et al. accelerated cancer growth in mice already having cancer. Nothing in Boros et al. teaches or suggests prevention of the promotion of possible cancer. Applicant asserts that Boros et al. is non-analogous art in the field of tumor cell biology and is improperly combined with Paradissis. The cited art does not provide motivation to delete vitamin B1, provided in Paradissis's composition to prevent acceleration of cancer in pregnant women. For at least these reasons, the rejection is inappropriate and should be withdrawn.

Boros (Anticancer Research, (2000 Vol. 29, No. 3B, pp 2245-2248, hereinafter Boros) analyzes food supplements in an epidemiological study. Boros speculates that "Excess thiamine supplementation in common food products may contribute to the increased cancer rates of the Western world" (Abstract, emphasis added). Boros further states, "In the present article, the naturally occurring enzyme thiaminase is introduced as a conceivable factor in controlling cancer rates in Asian and African countries..." (pp. 2246, first paragraph, emphasis added).

Paradissis discloses vitamins for pregnant women at different trimesters to promote fetal and maternal health. Paradissis's vitamin compositions comprise vitamin B1 and other ingredients for this purpose. Paradissis does not provide excess vitamin B1 in its compositions and does not administer vitamins in order to potentially contribute to an increased risk of cancer. Paradissis includes 1.0 to 2.0 mg of vitamin B1 in the vitamin compositions and does not administer excess vitamin B1. Boros states the RDA for thiamine in women is 1.0 mg (page 2245, first paragraph after the abstract).

One of ordinary skill in the art of Applicant's claimed invention would not look to Boros's epidemiological study about thiaminase activity in foods and different diets, and the potential carcinogenic effects of excess vitamin B1, for any guidance, suggestion or motivation to remove normal levels of vitamin B1 from Paradissis's composition and derive Applicant's claimed composition. Boros does not provide any such suggestion or motivation. Deletion of vitamin B1 from every embodiment disclosed by Paradissis could render these compositions of Paradissis unsatisfactory for their intended purpose or change their principle of operation, as supplements to be administered during the different trimesters of pregnancy. Boros et al. is non-analogous art, is improperly combined with Paradissis in this rejection, and provides no motivation to modify Paradissis's composition. For at least these reasons the rejection should be withdrawn.

Paradissis in view of Kostic

Claims 15-19, 22, 24, 30, 33, 41-45 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Paradissis et al. (U.S. Patent No. 5,494,678, hereinafter Paradissis) in view of

Kostic (Archiv fuer Gynaekologie, 1965, 202 (1) pp 506-509, hereinafter Kostic). Claim 46 was not rejected.

Applicants have discussed this cited art above with regard to the composition claims and those arguments are incorporated into this section of the response. The new claim amendments render the rejection moot. Applicant's method claims now recite treatment of hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss. Accordingly, the claim amendments and preceding comments render the rejection moot. Applicant requests withdrawal of the rejection and allowance of the claims.

Applicant's claimed composition is effective. As stated above, Applicant conducted a study concerning administration of one embodiment of the present invention to post menopausal women. This embodiment consisted of folic acid (1.6 mg), vitamin B12 (425 mcg), vitamin B6 (25 mg), vitamin D (400 IU) and calcium (400 mg), administered in two pills per day. Plasma homocysteine levels were measured before and six weeks after administration of the vitamin composition. The results show greater than a 20% reduction in plasma homocysteine levels in the postmenopausal women receiving the vitamin. These striking and unexpected results demonstrate the remarkable efficacy of Applicant's claimed vitamin composition. Paradissis and Kostic, alone or in combination, do not teach, suggest or provide motivation to practice Applicant's claimed methods, which are efficacious at least in post-menopausal women to reduce homocysteine levels. These surprising results are not taught or suggested by the cited art and are non-obvious in view of Paradissis and Kostic.

In view of the claim amendments and comments, the rejection is rendered moot and Applicant requests its withdrawal.

Paradissis in view of Boros et al. or Boros

Claims 15-19, 22, 24, 30, 33, 41-45 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Paradissis et al. (U.S. Patent No. 5,494,678, hereinafter Paradissis) in view of Boros et al. (Proc. Am. Assoc. Can. Res. Ann. Meeting (March 2000) No. 41, pp. 666,

hereinafter Boros et al.) or Boros (Anticancer Research, (2000 Vol. 29, No. 3B, pp 2245-2248, hereinafter Boros). Claim 46 was not rejected.

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Applicant's claimed composition is effective. As stated above, Applicant conducted a study concerning administration of one embodiment of the present invention to post menopausal women. This embodiment consisted of folic acid (1.6 mg), vitamin B12 (425 mcg), vitamin B6 (25 mg), vitamin D (400 IU) and calcium (400 mg), administered in two pills per day. Plasma homocysteine levels were measured before and six weeks after administration of the vitamin composition. The results show greater than a 20% reduction in plasma homocysteine levels in the postmenopausal women receiving the vitamin. These striking and unexpected results demonstrate the remarkable efficacy of Applicant's claimed vitamin composition. Paradissis and Boros et al. or Boros, alone or in combination, do not teach, suggest or provide motivation to practice Applicant's claimed methods, which are efficacious at least in post-menopausal women to reduce homocysteine levels. These surprising results are not taught or suggested by the cited art and are non-obvious in view of Paradissis and Boros et al. or Boros.

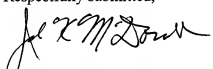
In view of the claim amendments and arguments, the rejection is rendered moot and Applicant requests its withdrawal.

CONCLUSION

Applicant submits that the pending claims define novel and patentable subject matter. Accordingly, Applicant respectfully requests allowance of these claims. No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required, or credit any overpayment, to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes any informalities remain in the application that can be resolved by telephone interview, a telephone call to the undersigned attorney is earnestly solicited.

Respectfully submitted,



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